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10/031,627	09/26/2002	Mark Anthony Fernance Kendall	KEMP002	8277

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EXAMINER

HAYES, MICHAEL J

ART UNIT PAPER NUMBER

3767

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.

10/031,627

<b>Applicant(s)</b>	
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KENDALL ET AL.

Examiner

Michael J. Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-41 and 55 is/are pending in the application.  
4a) Of the above claim(s) 8,35 and 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-34,36,37 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/15/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group II and species A (fig. 5) in the reply filed on 8/25/05 is acknowledged. The traversal is on the ground(s) that there is no serious burden to examine all the presented claims. This is not found persuasive because Applicant has not stated why there is no serious burden to examine all claims, but only states a conclusion. Applicant acknowledges that the application contains claims to independent or distinct inventions (See remarks pg. 10, received 8/25/05). In view of the independent or distinct inventions claimed and the burden to examine several species in one application the restriction is maintained. See MPEP 802. Claims 1-7 and 9-19, and claims 20 are combined in view of Applicant's amendment of 8/25/05.

This embodiments shown and described in the specification clearly specify the various species as shown in the figures. Applicant has elected fig. 5; therefore the claims directed to other species are withdrawn. The restriction between air-powered device, drive chamber pre-charged, membrane and duct of similar size, and having a starting process is not maintained and examiner agrees with Applicant's argument that these are not mutually exclusive species. See Applicant's remarks, pg. 10, received 8/25/05. Applicant has elected fig. 5 having one closure means and constant diameter driver chamber; therefore claims 8, 35, and 38-41 are further withdrawn as directed to a different species. Claims 8 and 38-41 are directed to a species having more than one closure means. Claim 35 is directed to a species where the driver chamber has a convergence positioned upstream of the closure means. Claim 20 is generic to these species.

The requirement is still deemed proper and is therefore made FINAL.

***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the spacer as recited in claim 33 and the indentation or scoring of the membrane surface as recited in claim 37 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Figures 1 and 2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated (see specification pg. 9, line 30 - pg. 10, line 3). See MPEP § 608.02(g).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claim 30 is objected to because of the following informalities: there appears to be a typographical error in line 2. "Are" should be "area". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 12, 30, 31, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 12, 31, and 32 recite the nozzle is contoured such as to cause "no oblique shock waves are formed in said substantially quasi-steady flow" and to cause "any expansion downstream of the duct section to provide a generally radially uniform particle distribution at the exit of the divergent portion and a generally radially uniform particle velocity distribution, with a substantially parallel velocity of particles and gas exiting the device." The specification states a contoured or simple correctly expanded nozzle achieves no oblique shocks and uniform flow, pg. 21, line 31 - pg. 22, line 1, but does not describe how the nozzle is contoured or simple to make the nozzle to enable these functions. There is no description of what Applicant regards as contoured or simple to enable one of ordinary skill in the art to make the claimed structure.

Claim 30 recites "divergent nozzle portion has an inlet cross-sectional are (sic) and an

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exit cross-sectional area, said areas being chosen in accordance with the total driver chamber pressure at which said device is arranged to operate so that, in use, the gas flow in said divergent portion is substantially correctly expanded when said particles pass through said divergent portion.” There is no description in the specification that enables one of ordinary skill in the art to choose the correct areas in accordance with the total driver chamber pressure. Applicant states a particular analytical function is employed to ensure correctly expanded flow on pg. 15, line 31 - pg. 16, line 5, but the analytical function is not disclosed.

Claim 10 recites a quasi-steady flow directed through said divergent nozzle portion is substantially correctly expanded. How to achieve correctly expanded and to make the device to achieve correctly expanded flow is not described. Applicant states that the nozzle exit area ( $A_e$ )/nozzle minimum area ( $A_1$ ) could range 1-50 (pg. 11, line 30 - pg. 12, line 5), but that this ratio is dependent upon the pressures within the nozzle (pg. 4, ll. 2-7). The specific correlation between the area ratio and nozzle pressures is not described.

Claim 18 recites the reflected expansion wave passing out the device end terminates the quasi-steady flow. The specification, page 15, ll. 11-21, states that the length of the driver chamber is critical in achieving this action, but there is no description of how long to make the driver chamber, particularly with respect to different gases (e.g. light or heavy) used. The specification does not describe what lengths are used to achieve these characteristics or how to calculate these lengths.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 24, 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the structure required to open the fluid connection (i.e., the bleed hole). In claim 24 the fluid connection is recited to be able to be opened and in claim 25 a bleed hole fluid connection is recited. "Fluidly connected" is an open arrangement, a bleed hole is only a space, and the structure and/or arrangement for opening (i.e., going from closed to open positions) the fluid connection and the hole is missing.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-12, 14-25, 26, 27, 29-32, 34, 36, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by BELLHOUSE et al. (US Patent No. 5,630,796). Bellhouse discloses a needless injection device and method of using the device including a rupturing membrane closure means (col. 8, ll. 1-5), substantially constant diameter driver chamber (upstream of rupturable membrane 34), substantially constant diameter duct section connected to

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driver chamber to receive gas therefrom, (constant diameter is within distal section of duct section, fig. 1), dose of particles P upstream of closure means 34, fig. 8, divergently contoured nozzle 38 (downstream of duct) through which a quasi-steady flow travels, whereby the device generates shock waves and reflection waves upon rupturing the membrane. A bleed hole is disclosed to provide the pathway from pressurized gas to the driver chamber and a bleed valve is understood in the art to be of small size that it would substantially decouple the driver chamber with pressurized gas source (col. 4, line 62 - col. 5, line 2). Nozzle areas are chosen with respect to driver chamber pressure to be correctly expanded (col. 5, ll. 22-33; col. 5, ll. 60-65; col. 6, ll. 5-7). Different gases are selected to give different velocities (col. 6, ll. 5-7).

Some limitations recited in the claims are considered inherent. Establishing quasi-steady flow upstream of shock waves, claims 1, 5, 20, entraining and accelerating particles in quasi-steady flow, claims 1, 20, initiating a starting process when shock wave reaches duct section end, claim 2, 21, producing a secondary shock wave behind primary shock wave, claim 4, uniform velocity distribution over a cross-section, claims 11, 32, no oblique shocks waves within the divergent nozzle, claims 12, 31, initiating (u-a) wave at duct end, claim 14, quasi-steady flow upstream of (u-a) wave, claim 15, expansion wave traveling upstream of membrane closure means, claim 16, and terminating quasi-steady flow when reflected expansion wave passes out of the device, claim 18 are considered inherent functions resulting from the generation of shock waves by rupturing a membrane at the downstream end of a driver chamber with a constant diameter duct section, and divergent nozzle.

The prior art discloses the same or similar structure recited in the claims and described in the specification with respect to fig. 5 and this similarity is the basis that the prior art device will



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inherently function as the claimed device and produce the associated waves and effects in use with shock waves. If Applicant argues that these claimed functions are not inherent Applicant should submit evidence that the prior art devices do not inherently possess these characteristics. See MPEP 2112, 2112.01, 2112.02.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9-18, 20-34, 36, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over HEINZEN (WO 97/47730) in view of BELLHOUSE (US Patent No. 5,899,880). Heinzen discloses a needless injection device (Fig. 1) and method of using the device including a rupturing membrane 18 closure means, driver chamber 13, constant diameter duct section 22, dose of particles in region of closure means 14, divergently contoured nozzle 24 through which flow travels, whereby the device generates an accelerated gas stream upon rupturing the membrane, and determining nozzle areas in accordance with pressures used in the device. The device is considered correctly expanded because the nozzle areas are chosen to correspond to the desired gas flow (pg. 10, line 3 - pg. 12, line 14).

Re claims 13 and 33 Heinzen discloses the claimed invention as per fig. 1, and discloses spacers 60 in the embodiment shown in figs. 4 and 5. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the embodiment shown in fig. 1

with the spacers seen in figs. 4 and 5 and described at pg. 21, ll. 9-28 in order to allow for reproducible results between subsequent deliveries, as described by Heinzen.

Re claims 6 and 27 Heinzen discloses the claimed invention except for placing the particles in an initial position upstream of the closure means. Bellhouse '880 teaches placing the particles in an initial position of closure means 34 which rupture to allow the particles to be injected (figs. 8, 8a, col. 9, line 60 - col. 10, line 8; col. 11, ll. 9-12). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Bellhouse '880 in the device and method of Heinzen in order to provide a replaceable capsule containing the particles to be injected.

Although disclosing releasing a pulse of compressed gas to achieve significant speed of injection, Heinzen does not disclose the gas flow as a shock wave, quasi-steady gas flows, or a bleed hole to de-couple the driver from gaseous fluid source. See figs. 1, 2a-c; pg.4, ll. 4-29; pg. 9, line 22 - pg. 10, line 2; pg. 10, line 28 - pg. 11, line 22; pg. 12, ll. 5-11; pg. 12, ll. 12-36. Bellhouse teaches the use of high gas pressure to generate a shock wave to achieve velocities for particle injection and a bleed hole to couple the driver chamber to a pressure source (col. 2, ll. 8-25; col. 3, ll. 58-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Bellhouse '880 in the device and method of Heinzen to achieve different gas pressures and velocities to achieve different depths of particle penetration.

Some limitations recited in the claims are considered inherent. Establishing quasi-steady flow upstream of shock waves, claims 1, 5, 20, entraining and accelerating particles in quasi-steady flow, claims 1, 20, initiating a starting process when shock wave reaches duct section end, claim 2, 21, producing a secondary shock wave behind primary shock wave, claim 4, uniform

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velocity distribution over a cross-section, claims 11, 32, no oblique shocks waves within the divergent nozzle, claims 12, 31, initiating (u-a) wave at duct end, claim 14, quasi-steady flow upstream of (u-a) wave, claim 15, expansion wave traveling upstream of membrane closure means, claim 16, and terminating quasi-steady flow when reflected expansion wave passes out of the device, claim 18 are considered inherent functions resulting from the generation of shock waves by rupturing a membrane at the downstream end of a driver chamber with a constant diameter duct section, and divergent nozzle. With regards to using a spacer, as a result of spacing the device end from the target tissue with a divergent nozzle it is inherent to create normal shock wave at divergent nozzle exit and to decelerate particles in normal shock wave having generally radially uniform velocity, claims 13, 33, due to the spacing. The prior art discloses a space similar to the space recited in the claims.

The prior art discloses the same or similar structure recited in the claims and described in the specification with respect to fig. 5 and this similarity is the basis that the prior art device will inherently function as the claimed device and produce the associated waves and effects in use with shock waves. If Applicant argues that these claimed functions are not inherent Applicant should submit evidence that the prior art devices do not inherently possess these characteristics. See MPEP 2112, 2112.01, 2112.02.

Claims 19 and 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over HEINZEN and BELLHOUSE '880 as applied to claims 1 and 36 above, and further in view of BELLHOUSE '478. Heinzen and Bellhouse '880 teach the claimed invention except for scoring the rupturable membrane and choosing different gas species to control particle velocities. Bellhouse '478 teaches scoring a rupturable membrane in order to limit shedding fragments (col.

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8, ll. 52-55) and selecting different gases to give different velocities (col. 6, ll. 15-44; col. 7, line 44 - col. 9, line 20). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Bellhouse '478 in the device of Heinzen and Bellhouse '880 in order to facilitate rupturing the membrane preventing unwanted material from traveling to the target site and to achieve different penetration depths with different gas velocities.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bellhouse (US Patent No. 6,010,478) and Bellhouse WO 96/12513 show needless injectors with rupturable membranes to create a shock wave to carry particles for injection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons, can be contacted at (571) 272-4965. The fax number for submitting official papers is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh  
22 December 2005



**MICHAEL J. HAYES**  
**PRIMARY EXAMINER**